INSTRUCTIONS FOR FILLING OUT THE FOR-OGITT-057. Edition No. 01 INTERNATIONAL FINAL REPORT

A. GENERAL CONSIDERATIONS

1. The form must be filled out in its electronic version available in the Peruvian Registry of Clinical Trials – REPEC. Then it must be printed, signed and presented at the INS Document Processing Office.

2. To access REPEC, the sponsor or its authorized legal representative in the country must be previously registered and must have a user account and password.
3. The administrator is responsible for ensuring that the data provided in this form is complete and truthful.

4. Once the information is entered in the form, REPEC automatically assigns a code
Report ID: INF-XXX
5. The International Final Report must be presented within twelve (12) months after the end of the clinical trial in all research centers internationally.
6. The final results and conclusions of the study must also be attached. The guidelines for the presentation, structure and content of the information to be presented are indicated in ***Annex 02 of the Manual of Clinical Trial Procedures: Guide for the report of results and conclusions of the clinical trial.***

B. FILLING OUT THE FORM

1. NOTIFYING INSTITUTION: 1.1. Institution

Name: Field generated automatically when entering the form, based on the recognition of the user account and password that was assigned to the institution.

1.2. Legal Representative: The person with current power of legal representative of the institution that sends the final report of the research center must be identified, as well as their contact information:

to. Names, Father's Last Name and Mother's Last Name: Enter as it appears in the identity document b. Identity

Document: (Number)

c. Telephone: Enter institutional contact information, not personal.

d. Email: Enter institutional contact information, not personal.

It is up to this person to sign the form for submission to the INS OGITT.

2. IDENTIFICATION OF THE CLINICAL TRIAL

Fields 2.1 to 2.7 are generated automatically during electronic registration in the REPEC based on the clinical trial that the administrator selects to report.

2.1. N° EC INS

2.2. Clinical trial title
2.3. Sponsor

2.4. Institution that legally represents the sponsor in the country
2.5. Clinical Phase of the study 2.6.

Protocol Code

2.7. Report date: Corresponds to the date on which the electronic form is completed (it is automatically generated by REPEC).

2.8. Final situation worldwide: Report how the study concluded in the world:
Select one of the following conditions:

to. The development of the protocol was complied with

b. Cancellation of the EC (Definitive interruption of activities, early or premature termination). Selecting this option implies that the clinical trial cancellation procedure is submitted (article 81 of the REC).

2.9. Start date of worldwide selection activities

It corresponds to the date of the first act of selection of a possible subject for the study, worldwide. The first act of selection corresponds to the date of initial contact with a potential research subject, unless another definition is expressly and clearly stated in the clinical trial protocol submitted to the OGITT.

2.10. Enrollment date of the first subject worldwide: Enter date in mm/dd/yy.

2.11. Enrollment end date worldwide: Enter date in mm/dd/yy.

2.12. Date of the last visit of the last research subject worldwide: Enter date in dd/mm/yy.

3. FINAL INFORMATION FROM THE CLINICAL TRIAL

3.1. Information regarding research subjects:
Complete regarding the number of participating subjects worldwide, including subjects who participated in Peru.

to. Screened subjects: These are the subjects who were invited to participate in the CS, signed informed consent and underwent a series of analyzes and/or visits to determine if they met the selection criteria and were not necessarily enrolled. Enter the total number.

b. Enrolled subjects: Screened research subjects who met the selection criteria indicated in the protocol and were finally included in the study. It must be recorded:

- Total number of subjects enrolled
- Number according to sex
- Maximum age: record the years (or months if applicable) of the oldest enrolled research subject. (The age at the time of enrollment is considered).
- Minimum age: record the years (or months if applicable) of the youngest enrolled research subject. (The age at the time of enrollment is considered)

c. Number of subjects who failed in the selection *(screen failure):* This number is deductible from the subtraction between the subjects who were screened and the enrolled subjects.

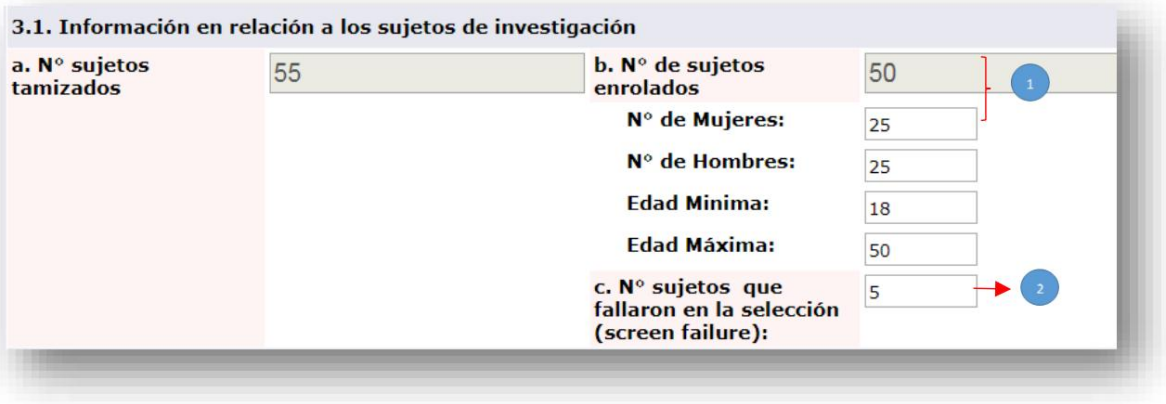
It should be noted that: + =

For this block **(a, b and** c), enter the information in the following order:

1st. No. of women and No. of men enrolled → The number of enrolled subjects **(b)** will appear by default

2nd. No. of subjects who fail in the selection **(c)** → The number of subjects screened **(a)** will appear by default

Complete the data regarding minimum age and maximum age.



d. Number of subjects who completed the study: Indicate the number of subjects who have completed the study, completing all scheduled visits.

and. No. of subjects who completed treatment: subjects who completed the treatment period according to the protocol.

F. Number of subjects who withdrew/abandoned the study: Indicate the number of enrolled subjects who did not complete the study, and must also specify the reason for withdrawal and abandonment:

- Due to withdrawal of consent from the subject: Indicate number.
- By decision of the researcher and/or sponsor: Indicate number and criterion considered (brief description) for example: Low Efficacy, adverse event, due to non-compliance with the protocol.
- Another duly specified cause: Indicate number and criterion considered (brief description)

4. ADDITIONAL COMMENTS OR OBSERVATIONS:

Any additional information that is considered important for the purposes of the International Final Report, that has not been requested in this form, can be entered in this section.

5. REGARDING THE RESULTS AND CONCLUSIONS OF THE CLINICAL TRIAL

According to article 105 of the REC, the final international report must be presented to the OGITT within twelve (12) months after the clinical trial has ended in all research centers internationally. The final international report must include the results

final results and conclusions of the clinical trial (article 2, section 2.1 Operational definitions, 16).

Therefore, you must submit FOR-OGITT-057 to the OGITT, attaching the final results and conclusions of the EC. The structure and content of this information is indicated in ***Annex 02 of the Manual of Clinical Trial Procedures: Guide for the Report of results and conclusions of the clinical trial.***

- **If at the time of submitting the *FOR-OGITT-057: International Final Report* the results and conclusions of the study will be attached, select the option:**

Results and conclusions are presented ☐

- **If you do not have this information as of the date of this report, select and complete:**

Shipping pending ☐ Estimated shipping date: ……./……/…… (dd/mm/yyyy)

Justification for delay in submission:

6. AUTHORIZED LEGAL REPRESENTATIVE

It corresponds to the section for the signature and date of signature of the legal representative of the Institution that presents the Report on behalf of the Sponsor, according to the data recorded in section 1.